AG

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,736	01/06/2004	Robert Vincent Martinez	31896-002000	2977

22204 7590 02/23/2006

NIXON PEABODY, LLP
401 9TH STREET, NW
SUITE 900
WASHINGTON, DC 20004-2128

EXAMINER	
YAO, LEI	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/751,736	MARTINEZ ET AL.	
	Examiner	Art Unit	
	Lei Yao, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 5-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 5-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/2/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed on 12/20/05 in response to the previous Non-Final Office Action (7/27/05) is acknowledged and has been entered.

Claims 3-4, 8-20 have been cancelled. Claims 1, 5, and 7 have been amended. Claims 33-36 have been added. Claims 1-2, 5-7 are pending and under consideration.

Information Disclosure Statement

The information disclosure statement (s) (IDS) submitted on 11/2/05 are/is considered by the examiner and initialed copy of the PTO-1449 is enclosed.

The following office action contains NEW GROUNDS of rejection.

Rejections Withdrawn

1. The objection of claims 1-2 and 5-7 because being drawn to non-elect3d invention is withdrawn in view of the amendments to the claims.

2. The rejection of claims 4-8 under *35 USC § 112 2nd* as being vague and indefinite because of its reliance upon tables within the specification is withdrawn in view of the cancellation of the claims.

3. The rejection of claims 1-2 and 5-7under under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in view of the amendments to the claims, which are claiming a method of diagnosing or monitoring colon cancer in a subject by detecting over expression of GPR49 protein.

4. The rejection of claims 1-2 and 5-7under *35 USC § 102* (e) being anticipated by Afar et al., (US Patent Application Publication, No, 2003/0232350, priority to Nov, 29, 2001) is withdrawn in view of the amendments to the claims, which are specifically claiming over-expression of GPR49 protein in colon cancer.

New Ground of rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2 and 5-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir,1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The instant claims are drawn to a method of a method of diagnosing or monitoring colon cancer in a subject comprising the step of detecting and comparing over expression of GPR49 protein in colon cancer tissues.

To satisfy the requirement of 112, 1st paragraph, it is necessary that the specification provide an enabling disclosure of how to make and use a claimed invention. The method objective of claims is to determine the presence of delta-catenin in the body fluid from a patient, who is suspected to have a prostate cancer. Thus, it would be expected that one of skill in the art would be able to use the method to diagnosing or monitoring colon cancer in a patient by detecting the levels of GPR49 protein in colon tissues.

The specification discloses a number of genes or polypeptides, which are suggested associating with colon cancer condition. The specification, on paragraph 0127, specially teaches that GPR49 (G protein-coupled receptor 49) is an orphan-G protein-coupled receptor with an unknown ligand. Expression of GPR49 gene has been reported in brain, skeletal muscle, placenta, and spinal cord. The specification, on the section of diagnostic assays (paragraph 374-376), generally teaches "a method for detecting the presence or absence of a colon cancer polypeptide (CCPP) in a biological sample involves contacting a biological sample with a compound or an agent capable of detecting the CCPP Suitable probes for use in the diagnostic assays of the invention are described herein" and "The diagnostic assays may also be used to quantify the amount of expression or activity of a CCG in a biological sample. Such quantification is useful, for example, to determine the progression or severity of colon cancer. Such quantification is also useful, for example, to determine the severity of colon cancer following treatment". However, the specification does not teach any working example, which specifically detects GPR49 protein in a cancer or normal colon tissue by using the method. The specification does not provide any teaching, which enables the claimed method of diagnosing or monitoring whether a patient is at risk of developing colon cancer by the levels of GPR49 protein in the colon tissues from a subject. Thus, the instant specification fails to disclose the necessary parameters for using the claimed method.

Morita et al., (Mol Cell Biol, vol 24, page 9736, 2004) teach GPR49 (LGR5) protein is related with embryonic development (abstract). Feder et al., (US patent application publication, US20030027323A1) describe (HGPRBMY5), which is 100% identical to GPR49 protein, highly expressed in brain and ovarian tissues (abstract). Currently, one skilled in the art has not

identified the association of the expression of GPR49 protein with normal or pathological condition comprising colon cancer. Instant application has not provided any enabled method or objective evidence demonstrating over-expression of GPR49 protein in colon cancer. Therefore, one skilled in art could not enable to use the claimed method for diagnosing or monitoring colon cancer by determining the levels of GPR49 protein in colon tissues

Since the specification does not provide claimed method for diagnosing or monitoring colon cancer by the levels of GPR49 protein in colon tissue, since the specification does not provide any guidance for indicating a patient at risk of colon cancer according the levels of the GPR49 protein in colon tissues, one skilled in the art would not know how to use the claimed method on the basis of teachings in the prior art or instant specification.

In view of the lack of objective evidence, lack of guidance, lack of examples, and lack of predictability associated with regard to diagnosing or monitoring colon cancer by the levels of GPR49 protein in colon tissue, one skilled in the art would be forced into under experimentation in order to practice the claimed invention. **If Applicants has any objective evidence contrary to the rejection, Applicant is invited to submit it to the Office for reconsideration**.

Conclusion

Therefore, NO claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-4.30pm Monday to Friday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao, Ph.D.
Examiner
Art Unit 1642

LY